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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,067	01/14/2004	Mohinder Singh	CU-3536 BSE	4134

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
12/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,067	SINGH, MOHINDER	
	Examiner	Art Unit	
	Snigdha Maewall	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/09/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's Arguments/Remarks, amended claims and IDS filed on 10/09/2007 is acknowledged.

Claims 1-16 are pending in this application. Claims 1 and 16 have been amended.

Claims **1-16** will be prosecuted on the merits.

The following rejections are maintained.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-7 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faust (US Patent No. 4,822,597) in view of Sixsmith (US patent No. 5,322,694).

Faust discloses a composition, which relates to chewing gum comprising anesthetics such as benzocaine, lidocaine etc which readily release the anesthetics such that it is available to anaesthise the throat and mouth areas, thereby providing relief to irritated areas. The amount of anesthetic that can be present is from about 0.05% to about 0.5% (column 2, lines 5-10). The composition includes sweetener such as hydrogenated starch hydrolysate, sucralose and sugars like sucrose, glucose dextrose and fructose (column 4, lines 1-5 and lines 13-16). Flavoring agents such as mints, peppermint and spearmint can be added in the composition; artificial vanilla, cinnamon and kola extracts are shown to be added to the composition. Menthol oil, ginger oil and clove oil can also be added (column 4, lines 33-50).

Faust does not teach gelatin and silica in the composition. However, Sixsmith teaches gelatin and silica.

Sixsmith discloses a gelatin treated polyhydric alcohol compositions, their preparations to pharmaceutical lozenges (abstract). Local anesthetics that are used in the composition are benzocaine. The quantity of anesthetic required can vary widely and ranges from about 1-20 mg (column 5, lines 1-2). Excipients such as mannitol and colloidal silica are used in the composition (column 2, lines 5-9). The pharmaceutical dosage forms are used to treat conditions such as throat infections and thus inherently relieves pain.

Since the composition provided by Sixsmith comprising gelatin and silica helps in treating throat infections, it would have been obvious to the one of ordinary skilled in the art to incorporate gelatin and silica in the composition forwarded by

Faust. A skilled artisan would have been motivated to make a formulation comprising benzocaine or any other anesthetic along with sucralose, sugars, hydrogenated starch hydrolysate and gelatin with a reasonable expectation of success. With respect to various percentage amounts of the various components in the composition, it is the position of the examiner that such a parameter can be optimized with experimental manipulations. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

4. Applicant's arguments filed 10/09/2007 have been fully considered but they are not persuasive.

Applicants argues that " Applicants can find nowhere within Faust, Sixsmith and Mackles, that disclose or suggests a soft, chewable anaesthetic lozenge Containing 1-20% by weight of hydrogenated vegetable oil.". This argument is not persuasive because examiner has cited menthol oil as hydrogenated vegetable oil (column 4, lines 33-50, Faust reference). Menthol is hydrogenated oil based on the reference cited as of interest to support the argument. (see reference attached by Alberto et al. (Liquid phase hydrogenation of dementholized peppermint oil) which discloses that menthol is prepared by hydrogenation of menthone or hydrogenation of dementholized peppermint

oil to menthols. Thus it is the examiners position that the claimed hydrogenated vegetable oil reads on menthol oils as taught by Faust. Furthermore applicant has not specified specific vegetable oil, in the absence of such any vegetable oil which has been hydrogenated reads on the claimed limitation. With regard to the argued limitation of the specific amount, it is the position of the examiner that optimization of various amounts can be manipulated by doing experiments in order to obtain result oriented effective amounts. Applicant has not shown any unexpected results associated with the claimed amounts. It is further pointed out that in response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Faust teaches a lozenge with anesthetic and Sixmuth also teaches anesthetic and other embodiments as claimed, therefore it would have been obvious to one of ordinary skilled in the art to prepare an anesthetics based on the teachings and guidance of the cited references.

The rejection is therefore maintained.

5. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faust (US Patent No. 4,822,597) In view of Sixsmith (US patent No. 5,322,694) and

further in view of Mackles (US patent No. 4,260,596).

The teachings of Faust and Sixsmith have been discussed above.

Faust in combination with Sixsmith does not teach polyethylene glycol of between PEG-4 and PEG-800. However, Mackles discloses an edible unit dosage form capable of delivering liquid or soft gel product comprising benzocaine, mannitol, sorbitol, sugars and PEG-75 along with other excipients (abstract and column 3, lines 58-62). Since PEG 75 has been used effectively to produce an edible dosage form; it would have been obvious to one of ordinary skilled in the art at the time the invention was made to incorporate PEG-75 in the composition forwarded by Faust and Sixsmith. A skilled artisan would thus have been motivated to formulate a lozenge with PEG-75 along with other ingredients such as benzocaine, sugars, hydrogenated starch hydrolysate etc. as discussed above with a reasonable expectation of success.

Response to Arguments

6. Applicant's arguments filed 10/09/2007 have been fully considered but they are not persuasive. Applicant argues" As per MPEP 2143.03, a prima facie case of obviousness requires that the combined prior art references teach or suggest al._/of the claimed limitations. Since Faust, Sixsmith and Mackles, do not disclose or suggest a soft, chewable anaesthetic lozenge containing 1-20% by weight of hydrogenated vegetable oil, then Faust, Sixsmith and Mackles, in whole or in combination, cannot support an obviousness rejection to independent claims 1 and 10, as amended."

This argument is not persuasive because as discussed above Faust and Sixmuth teach a lozenge comprising claimed components and Mackles has been cited for Polyethylene glycol. It is to be noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

The rejection is therefore maintained.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-

272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

Art Unit 1615

Gollamudi S. Kishore, PhD
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